Cobalt-60 Supply Chain and Market Study

Jodi LIEBERMAN	Sandia National Laboratories
Michael ITAMURA	Sandia National Laboratories
Vanessa VARGAS	Sandia National Laboratories
Joseph ADDUCI	Argonne National Laboratory
Matthew KESKULA	Argonne National Laboratory

Sandia National Laboratories is a multimission laboratory managed and operated by National Technology and Engineering Solutions of Sandia LLC, a wholly owned subsidiary of Honeywell International Inc. for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-NA0003525. SAND2021-1958 O

Outline

Study Objectives

Summary of Completed Phases

Answers from Workshop Roundtable

Phase 2 and Next Steps

e-beam radiation processing facility
Image courtesy of IBA Industrial

Co-60 Source Rack
Image courtesy of STERIS AST steris-ast.com

Study Objective

EXAMINE THE COSTS, BENEFITS AND REALITIES associated with operating a gamma industrial panoramic irradiator facility in comparison to a comparable non-radioisotopic irradiator replacement.

Methodology

The study examines costs, benefits, and capabilities for three scenarios:

- Fully transition an existing Co-60 facility to an alternative technology facility.
- Selecting Co-60 or an alternative technology for construction and operation of a new irradiation facility
- Developing parallel operation by adding alternative technology at an existing Co-60 irradiation operations, potentially eventually phasing out radiological sources.

Study Phases

0 1 2 C

Phase 0

Industry Scope Definition, Survey past DOE market studies

Determining subset of industry sectors and regional focus

Phase 1

Research the impacts of changing regulatory environment surrounding irradiation treatments

Conduct a deep dive on the cobalt marketplace.

Utilize prior comparative studies and assessments between alt-tech and gamma as a method of displaying the value of cost-saving for alt-tech options when possible.

Impact of ongoing EO legislation and shutdowns, and COVID-19, on the radiation sterilization marketplace.

Engage with industry to identify consistent drivers and perceptions of market impact.

Study Phases *(continued)*

0 1 2 C

Phase 2

Creating a decision strategy based on data compiled in Phase 0 & 1 from market data and other indicators

Develop a generic metric that can allow a facility to analyze if alternative technology may be viable

Project Conclusion

Develop data for future engagement on alt-tech development

Phase 0

0 1 2 C

Objectives

Industry Scope Definition and Outline

Survey past DOE market studies

Determining subset of industry sectors (i.e. sterilization, phytosanitary) that will be the focus of economic study

Decide on regional focus of the study: domestic and international, domestic, or just international

Conclusions

The marketplace for cobalt-60 panoramic irradiators is complex.

- Cost comparisons of sterilization modalities across market sectors are difficult, although they can be done on a site-specific level.

Market and regulatory barriers hamper the transition to both E-beam and X-ray technology, though E-beam has developed a small market niche given its technical capabilities.

Demand for sterilization services (both in the medical and food sectors) is likely to increase.

Phase 1

0 1 2 C

Objectives

Research the impacts of changing regulatory environment surrounding irradiation treatments, especially if upcoming laws and trends suggest a need for future food or medical sterilization (i.e. EO).

Conduct a deep dive on the cobalt marketplace.

Utilize prior comparative studies and assessments between alt-tech and gamma as a method of displaying the value of cost-saving for alt-tech options when possible.

Impact of ongoing EO legislation and shutdowns, and COVID-19, on the radiation sterilization marketplace.

Engage with industry to identify consistent drivers and perceptions of market impact.

Phase 1

0 1 2 C

Conclusions (in progress)

Review of Comparison Studies

- Most studies indicated that E-beam and X-ray could be economically viable compared to Co-60 irradiation, both in the short and long term.
  - Differing assumptions about product densities, throughput rates, and the costs of electricity or cobalt reloading led to different conclusions about cost benefits of machine-based sources.
- Specific price points at which accelerators may become more cost-effective than Co-60 are hard to meaningfully determine given the number of relevant inputs to cost calculations
  - Such analyses at individual facilities are more viable
- Most studies indicate that accelerator-based systems become more efficient as throughputs increase

Participation in Fermi Workshop on Medical Device Sterilization

0 1 2 C

As part of the Phase 1 efforts to engage with industrial irradiation stakeholders, the study team attended two workshops on medical device sterilization hosted by Fermi:

September 18-19, 2019

September 17, 2020 (Virtual)

Workshop Participation and Roundtable Engagement

Organizing Committee of the Medical Device Sterilization Workshop on Medical Device Sterilization

- Study team held roundtable Discussion on:
- "Industry interest in alternative radiation technologies in light of current events"

The study team created a questionnaire for the attendees.

- A total of 43 responses were gathered from the attendees. These responses were broken down as follows:

Participant Industry	Count
Consultant/Trade Association	4
Government	3
Medical Device/Pharmaceutical Manufacturing	15
Research and Development	3
Sterilization Service Provider	18

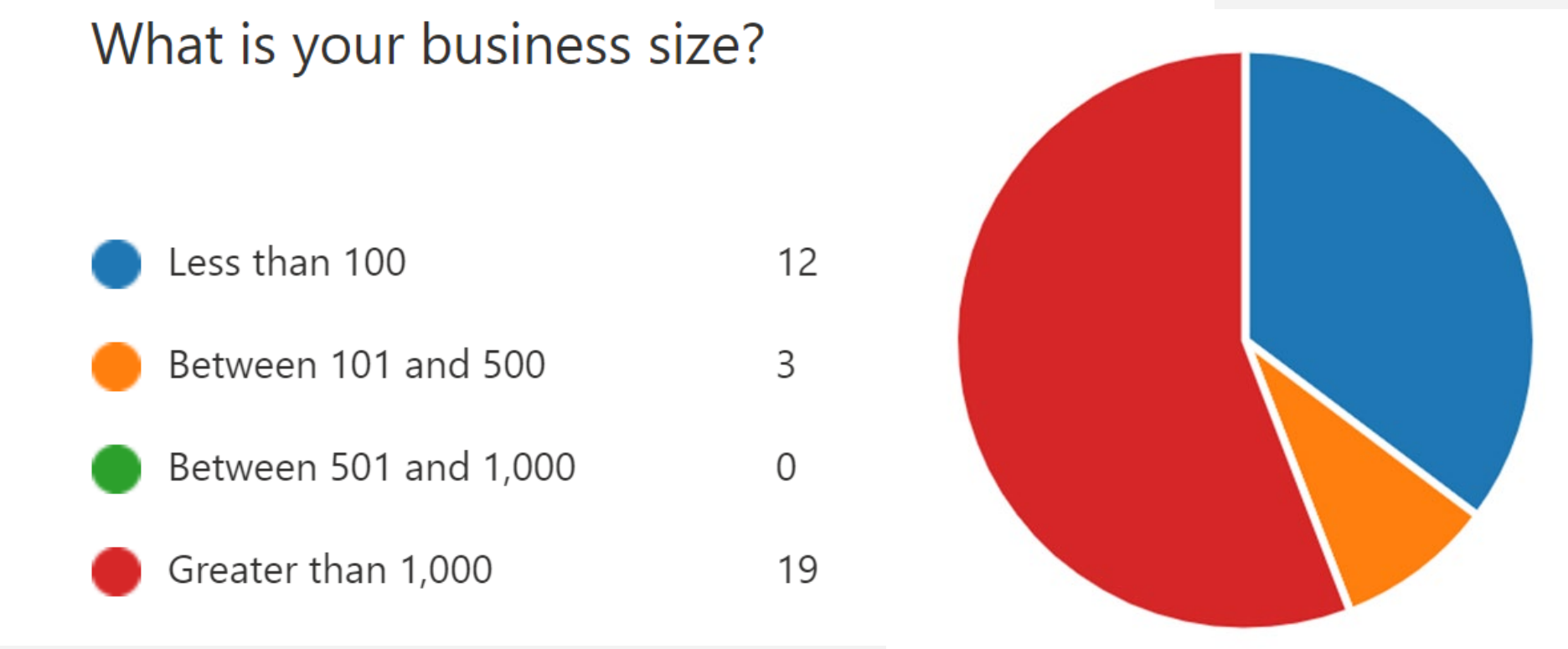
Roundtable Questionnaire

Participants were given the opportunity to submit expanded answers, which proved valuable when interpreting the results.

22 Questions for 4 Sections

- Business Information
- Industry Perceptions
- Future Trends/Issues in Marketplace and Potential External Impacts
- World Events and Future Considerations

Survey Demographics



Survey Demographics

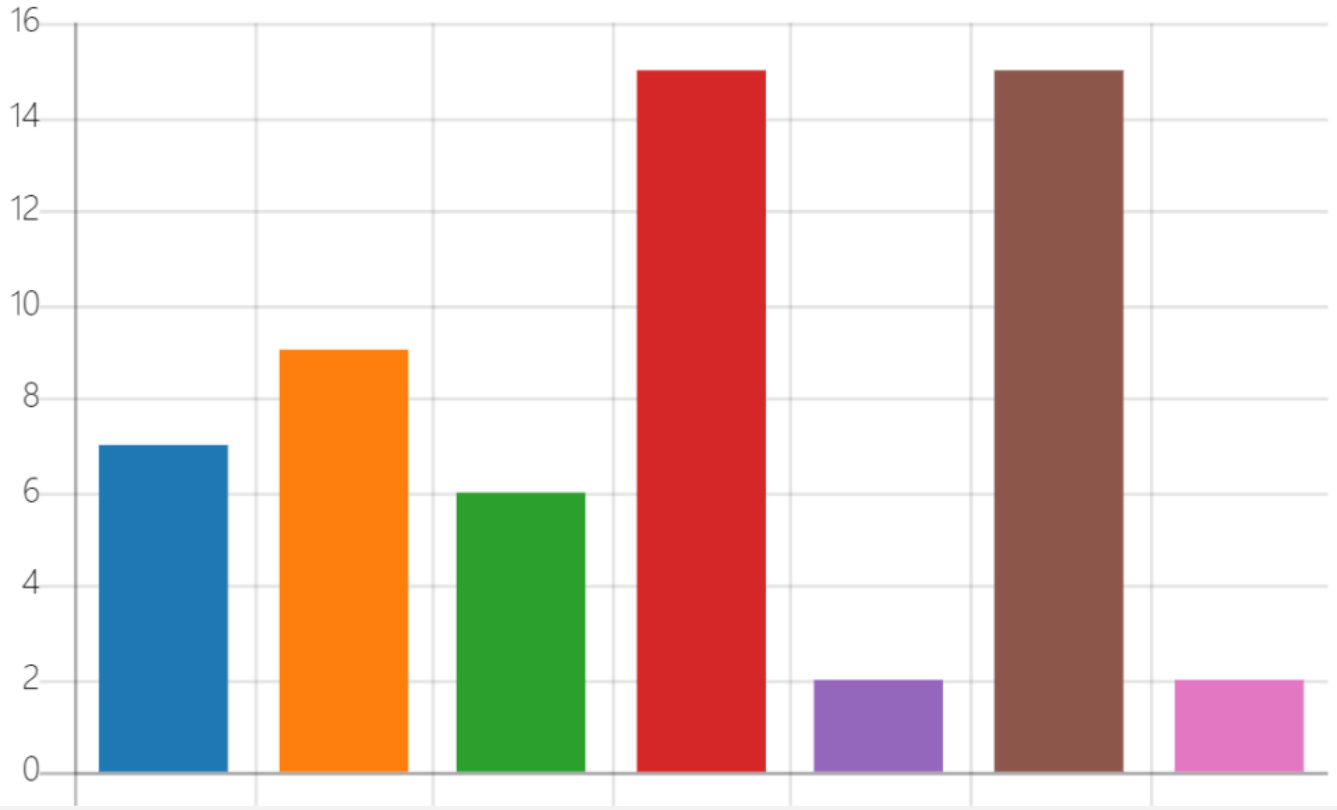
What does your company do? Please select all that apply.

Sterilization Services Provider (for External Customers)	9
Sterilization Services Provider (for "In-House" Products)	7
Medical Device/Pharmaceuticals Manufacturing	21
Sterilization Technology/Sub-Unit/Accessory Provider	5
Other	10

Survey Demographics

If you are a sterilization provider, what modalities do you use? Please select all that apply.

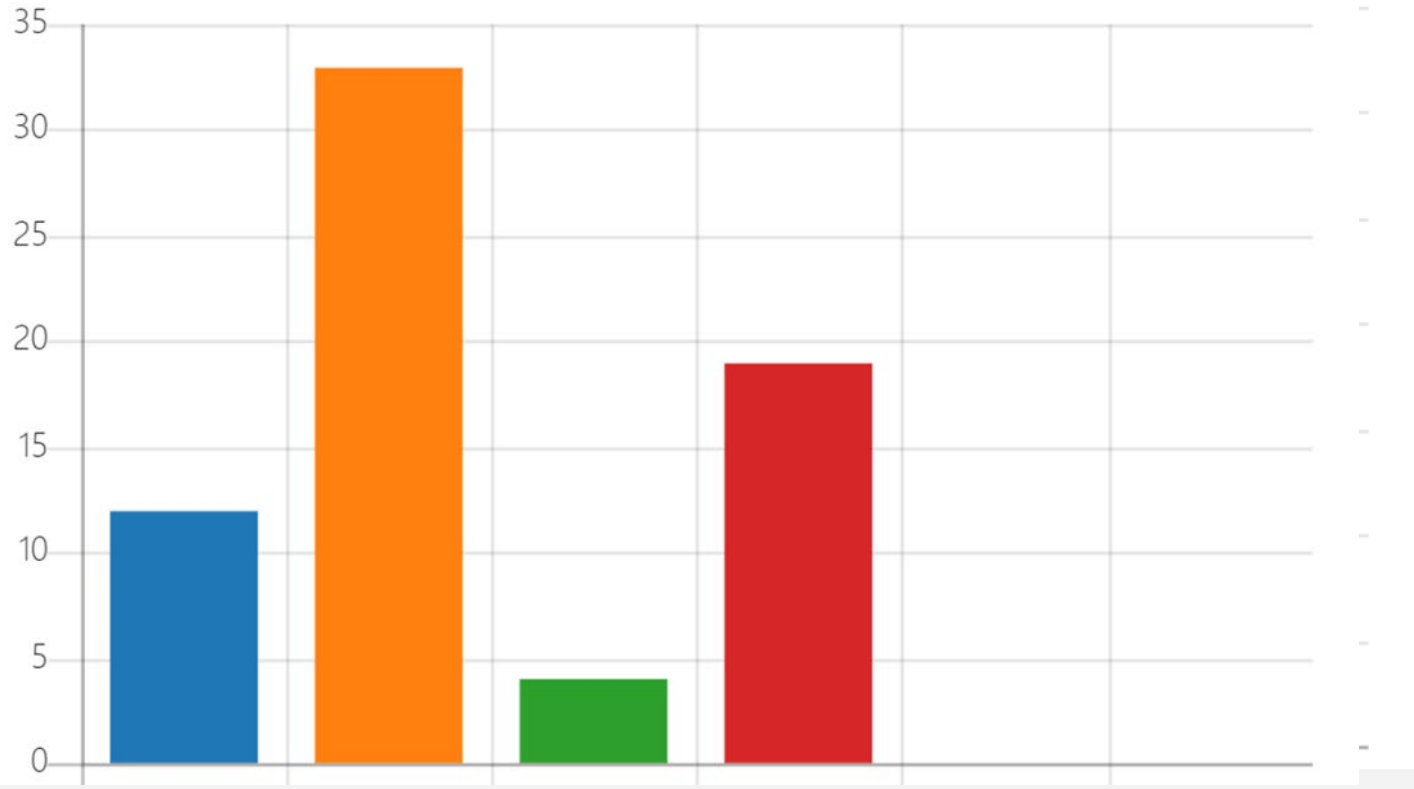
Gamma radiation	7
Ethylene Oxide	9
X-ray	6
eBeam	15
Vaporous Hydrogen Peroxide	2
Not Applicable	15
Other	2



Survey Question Results

In the next five years, do you see the medical device sterilization industry? Please select all that apply.

Utilizing more gamma sterilization services (e.g. Co-60)	12
Utilizing more machine sources of irradiation (eBeam/X-ray)	33
Utilizing more Ethylene	4
Utilizing more of the other sterilization modalities	19
None of the above	0
Other	0



Survey Question:
Future of Medical Device Sterilization Industry

Growth will come from EBeam/X-Ray and new modalities/technologies

- EtO and Gamma use will continue to be widespread, especially with COVID-19

Concerns about the long-term supply of Cobalt 60, this is also a monopoly.

- Cost of gamma irradiation continues to increase
- Nature of our custom Single Use Assemblies (non -homogeneous, varying geometries/densities) used for pharmaceutical drug manufacturing, may benefit from X-ray sterilization.

Over the next 10 years volumes of DMD will almost double.

- Industry can not rely on the two existing main modalities (Gamma and EtO) for all the reasons we know.
- The only existing alternative with for H-volumes capability is E-beam and X-ray.
- Also, thanks to the great DUR and high dose rate, ALL products irradiated today in Gamma can be sterilized in X-ray.

Survey Question:
Barriers to Non-Gamma Sterilization

Please list any barriers or concerns your company has when considering would it take to construct additional non -gamma irradiation -based sterilization infrastructure

- Moving from a batch process to an in -line process would require significant changes in the manufacturing process and facilities.
- Regulatory acceptance for X-Ray, cost of validating sterilization of existing/new devices to irradiation -based methods, cost of new sterilization infrastructure, lack of experience/understanding with irradiation -based methods (esp. X-Ray)
- Resources and funding from R&D to investigate alternate modalities for current product portfolio, and commitments from Development engineers to investigate alternate modalities for new products.
    - Also, availability of X-ray technology is scarce, so material investigations are difficult to perform

Phase 2 Objectives

Phase 2 is in early stages

Creating a decision strategy based on data compiled in Phase 1 (e.g., marketplace data, industry drivers)

Develop a generic metric that can allow a facility to analyze if alternative technology may be viable.

Utilize market data and other indicators to identify nascent markets where early alt-tech engagement may find success.

Develop lessons learned for future engagement on alt-tech development.

Effects of COVID-19 on Sterilization Market Trends

Demand for medical device sterilization, including radiation and EO, has also increased as a result of Covid-19

China National Nuclear Corporation prioritized use of radiation over EO to sterilize medical protective suits

- Reduces sterilization time to hours from the 7-14 days for EO alone
- The combination of Cobalt-60 and EO is more expensive than using EO alone
- Cost increase is due to clothing needing to be tested for radiation resistance

EO alone is capable of adequately sterilizing N95 masks

- The FDA pushed for reopening of previously closed EO sterilization facilities during the early stages of the pandemic

Increased global demand for PPE and precursors

- Greater burden on the sterilization sector
- Demand for EO devices has also increased as a result of Covid-19

Path Forward

Phase 1 nearing completion

- Discussions with industry has been problematic

Phase 2 underway

- Consolidation of compiled research is currently underway

- Expected Completion - Summer 2021